



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,985	01/16/2004	Raymond F. Schinazi	EMU133 CON 5 18085.105302	8318
7590 Sherry M. Knowles 45th Floor 191 Peachtree Street, N.E. Atlanta, GA 30303			EXAMINER CRANE, LAWRENCE E	
			ART UNIT 1623	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/10/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/759,985	<b>Applicant(s)</b> SCHINAZI ET AL.	
	<b>Examiner</b> L. E. Crane	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12 and 14-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12 and 14-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

No additional claims have been cancelled, claim **33** has been amended, the disclosure has been amended at page 28, and no additional new claims have been added as per the amendment filed July 31, 2006. No additional Information Disclosure Statements (IDSs) filed has been received with copies of all newly cited references and made of record.

Note to applicant: Because of the failure to date of the PTO to copy paper files of parent cases, applicant is advised that one way the vast majority of reference citations will be made of record in the scanned document database for this application would be for applicant to submit copies of same for scanning.

Claims **12 and 14-33** remain in the case.

Claims **12 and 14-33** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **12** at line 3 the term "an HIV related opportunistic infectious disease" is generic and is not accompanied in the instant claim by any listing of all such infections which are intended to be treated, thereby rendering the instant claim incompletely defined. See also claim **16** wherein the same term also appears.

Applicant's arguments filed July 31, 2006 have been fully considered but they are not persuasive.

Applicant has argued that one of ordinary skill would know the identity of all HIV-related opportunistic infections, and therefore that the above term is not indefinite. This presumes that the knowledge of this class of infections is complete and that the instant treatment will be effective against all infections included within the generic class, regardless of whether the disease conditions are presently known, or not known. In light of the limited data provided in support of the instant assertion, examiner has maintained the above rejection.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA

1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **12 and 14-33** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-10** of U.S. Patent No. **6,680,303** (PTO-892 ref. **G**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment of HIV and the alleged active ingredients are directed to substantially overlapping subject matter because the instant claims are directed to a method of treating diseases which only occur when HIV has compromised the immune system, a condition which nucleoside analogues are well known to be capable of reversing by suppressing HIV and thereby permitting immune function to be reestablished.

Claim **12 and 14-33** is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-10** of U.S. Patent No. **6,391,859** (PTO-892 ref. **A**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment of HIV and the alleged active ingredients are directed to substantially overlapping subject matter because the instant claims are directed to a method of treating diseases which only occur when HIV has compromised the immune system, a condition which nucleoside analogues are well known to be capable of reversing by suppressing HIV and thereby permitting immune function to be reestablished.

Claim **12 and 14-33** is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-10** of U.S. Patent No. **6,232,300** (PTO-892 ref. **B**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment of HIV and the alleged active ingredients are

directed to substantially overlapping subject matter because the instant claims are directed to a method of treating diseases which only occur when HIV has compromised the immune system, a condition which nucleoside analogues are well known to be capable of reversing by suppressing HIV and thereby permitting immune function to be reestablished.

Applicant's arguments filed July 31, 2006 have been fully considered but they are not persuasive.

Applicant has acknowledged the above rejections, has not argued against same, but has thus far failed to supply any Terminal Disclaimers. Therefore, the above grounds of rejection have been maintained.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

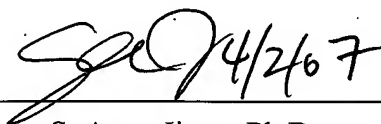
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

Art Unit: 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec  
04/01/2007



S. Anna Jiang, Ph.D.  
Supervisory Patent Examiner  
Technology Center 1600